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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,473	01/21/2004	John C. Rueter	P0011409.00	4388

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EXAMINER	
GEDEON, BRIAN T	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
09/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/761,473	RUETER, JOHN C.	
	Examiner	Art Unit	
	Brian T. Gedeon	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 August 2008 has been entered.

Claim Rejections - 35 USC § 112

2. The 35 U.S.C. 112, second paragraph, rejection for indefiniteness against claims 1-10 and 12-20 has been withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 6, 11, 12, 16, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Jorgenson et al. (US Patent no. 6,317,633).

In regard to claims 1, 11, 12, and 22, Jorgenson et al. describe an implantable pulse generator (IPG) 26 sealed in housing 18, col 7 lines 49-59. Electrodes 20 and 22

are carried on lead 16 and electrodes 28 and 30 are carried on lead 14, and are coupled to the IPG to deliver electrical stimulus pulses to cardiac tissue, col 7 line 60 - col 8 lines 13. A microcomputer 302 contains a microprocessor 304 to control the operational functions of the IPG, col 10 lines 66-67 and col 11 lines 33-35. A lead impedance test circuit 342 conducts a lead status monitoring (LSM) test to process information regarding the function of the implantable leads by measuring the impedance of a lead, col 5 lines 57-60, 64-65, col 6 lines 23-26, col 9 lines 6-23, and col 13 lines 44-46. Jorgenson et al. are concerned with lead status, based on impedance, because lead breakage impedes sensing conditions causing cardiac signals to be attenuated or distorted. Lead status also affects cardiac pacing procedures because increase impedance in the path of pacing signal reduces the effective pacing pulse energy, thereby resulting in loss of capture, col 3 lines 1-23. When loss of capture occurs, it is known that the threshold energy required to achieve capture is increased. Therefore, in view of this teaching, it is considered that increased lead impedance is an indicator of a likely increase in threshold required to effectively capture the heart. The test for lead impedance, according to Jorgenson et al. is done in the absence of a threshold test that delivers pacing pulses. Further, Jorgenson et al. teach that it is well known to apply a safety margin between the delivered pacing pulse and the stimulation threshold in order to ensure capture occurs, col 13 lines 19-28.

In regard to claims 6, 16, and 21, Jorgenson et al. teach that a threshold increase indicator may be associated with lead impedance, col 3 lines 1-23

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2-5 and 13-15 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Jorgenson et al. (US Patent no. 6,317,633) in view of Lu (US Patent no. 6,687,545).

In regard to claims 2-5 and 13-15, Jorgenson et al. substantially describe the invention as claimed except for the setting of a time interval/timer over which a safety factor is maintained until the timer either expires, or another indicator of increase threshold is detected. Lu, in a similar field of endeavor, describes an implantable cardiac stimulation system 10 in communication with a patient's heart via leads 20, 24, and 30, col 5 lines 35-45. The system 10 performs tests for when a change in capture threshold occurs, col 1 lines 8-13. Lu also sets a timer, that upon expiration, will determine if the enhanced stimulation signal containing a safety margin is still necessary to ensure capture. If it has been determined that the enhanced signal is not necessary, the stimulation energy is adjusted (i.e., decreased to a lower level), col 14 lines 22-30. Within the timer duration, the device of Lu also looks to see if indicators of increased threshold exist, and resets the timer accordingly, col 14 lines 7-50. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Jorgenson et al. to revert stimulation energy to a lower

predetermined level when the need for increased threshold stimulation is no longer determined necessary since Jorgenson et al. teach that stimulation at an unnecessary energy level is wasteful to battery energy, col 3 lines 19-23.

7. Claims 7-10 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgenson et al. (US Patent no. 6,317,633) in view of Ferek-Petric (US Patent no. 7,317,943).

In regard to claims 7-10 and 17-20, Jorgenson et al. substantially describe the invention as claimed including that physiological changes in the patient may result in altered threshold values, col 13 lines 24-28. Ferek-Petric describes an implantable cardiac pacing device that tests for capture, col 1 lines 61-63. Ferek-Petric teaches that capture thresholds change in relation to changes in cardiac parameters, wherein "cardiac parameters" may pertain to physiological or non-physiological factors. Physiological factors include changes in blood pressure, a change in the cardiac waveform, a change in the hemodynamics of the patient, or in the heart contractility, col 2 lines 13-18. The Examiner considers that arrhythmia and refractory events to be included in the factors described by Ferek-Petric, or in the least well-known obvious equivalents. Non-physiological factors are described as pertaining to the performance of the implantable device, col 2 lines 10-13; in which the Examiner considers a mode switch to be included. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Jorgenson et al. in view of Ferek-Petric to include the physiological and non-physiological indicators of an increase in

threshold, since Ferek-Petric teaches that it is known in the art to monitor for these indicators when testing threshold requirements.

Response to Arguments

8. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Stroebel (US Patent no. 5,861,012) describe a threshold testing pacemaker.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

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Examiner
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